K113250

Dynatronics
7030 Park Centre Drive • Salt Lake City, Ut 84121
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FEB - 9 2012

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

26 October 2011

SUBMITTED BY: DYNATRONICS CORPORATION
7030 Park Centre Drive
Salt Lake City UT 84121
Phone: (800) 874-6251; (801) 568-7000
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1. DEVICE NAME:

Trade Name(s):	Dynatron Tri-wave™ light pad (model number DLP3) Dynatron Tri-wave™ light probe (model number DCP3)
Common Name:	Topical heat lamp
Classification:	Class II
Regulation Nos.:	890.5500
Product Codes:	ILY

2. PREDICATE DEVICES:

Dynatron X_P Infrared Pad, cleared under K051261 (July 25, 2005) as the predicate for the Dynatron Tri-wave™ light pad

D880 Infrared Probe, cleared under K031329 (Oct 22, 2003) as predicate for the Dynatron Tri-wave™ light probe

3. DESCRIPTION:

The Dynatron Tri-wave™ light pad and Dynatron Tri-wave™ light probe generate therapeutic topical heating treatments through the medium of multi-wavelength light energy to targeted tissue.

The Dynatron Tri-wave™ light pad is a bifurcated pad with two 5" x 7" treatment pads connected by a 24" cable between them and a 72" cable connecting to the *Dynatron Solaris* PLUS™ controlling console. The two pads accommodate treating both sides of a shoulder, elbow, knee, etc. or may be used side by side to treat larger areas such as the lower back.

The Dynatron Tri-wave™ light probe is designed with super luminous diodes emitting three different wavelengths of light. The Infrared LEDs have a wavelength of 850nm, the Red LEDs have a wavelength of 624nm and the Blue LEDs have a wavelength of 464nm. The light probe handle has an ergonomic design and is suited for treating small areas such as the hand, wrist or neck.

Accessories:
Protective eyewear

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4. INTENDED USE/INDICATIONS FOR USE:

The Dynatron Tri-wave™ light pad and Dynatron Tri-wave Light™ Probe use light therapy to provide topical heating for the following indications:

Temporary increase in local blood circulation
Temporary relief of minor muscle and joint aches, pains and stiffness
Relaxation of muscles
Muscle spasms
Minor pain and stiffness associated with arthritis

The Intended Use/Indications For Use stated herein are consistent with the cleared indications for the predicate devices.

5. TECHNICAL ANALYSIS:

The Dynatron Tri-wave™ light pad and Dynatron Tri-wave™ light probe generate therapeutic benefit as described in allowed claims through the delivery of mulit-wavelengths of light:

Infrared (850nm)
Red (624nm)
Blue (464nm)

The predicate pad and probe operate with one primary wavelength of light.

Controls and power for the Dynatron Tri-wave™ light pad and Dynatron Tri-wave™ light probe are the same as with the predicate devices via a controlling console. Pause and re-start functions for the Dynatron Tri-wave™ light probe are activated by user interface on the probe but controlled by *Dynatron Solaris* PLUS™ controlling console. Treatment setup, start and stop functions for the Dynatron Tri-wave™ light pad are controlled by the *Dynatron Solaris* PLUS™ controlling console user interface.

Performance characteristics:

Dynatron Tri-wave™ light pad is comprised of the following recommended treatment combinations:

Infrared (850nm) and Red (624nm)
Blue (464nm) and Infrared (850nm)
Blue (464nm), Infrared (850nm) and Red (624nm)
Infrared (850nm) only

Dynatron Tri-wave™ light probe is comprised of the following recommended treatment combinations:

Infrared (850nm) and Red (624nm)
Blue (464nm) and Infrared (850nm)
Blue (464nm) Infrared (850nm), and Red (624nm)
Infrared (850nm) only

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6. SUBSTANTIAL EQUIVALENCE (SE) RATIONALE:

The Dynatron Tri-wave™ light probe and Dynatron Tri-wave™ light pad provide topical heating for treatment of selected medical conditions and share the same or similar basic characteristics, features and intended uses as the predicates and, therefore, are substantially equivalent to the Dynatron X_P pad and Dynatron D880 light probe (applicable 'K' numbers listed above).

7. SAFETY AND EFFECTIVENESS SUMMARY:

There are no substantive differences between the products defined in this 510(k) submission and the predicate devices. They are similar to the technologies that are currently used in other similar medical devices. They are subject to development and documentation under Dynatronics' mature Quality Management System, under the Quality System Regulation, 21 CFR Part 820, under design/change control, and are subject to verification and validation to applicable standards/guidance documents. The Dynatron Tri-wave™ light family of multi-wavelengh light therapy devices are safe and effective when used as indicated in specific applications under a clinician's supervision/therapy program.

Signed: Douglas G. Sampson Dated: 26 OCTOBER 2011

Douglas Sampson, VP, R&D and Operations
DYNATRONICS CORPORATION

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB - 9 2012

Dynatronics Corporation
% Mr. Douglas Sampson
7030 Park Centre Drive
Salt Lake City, Utah 84121

Re: K113250
Trade/Device Name: Dynatron Tri-wave™ Light Pad
Dynatron Tri-wave™ Light Probe
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: ILY
Dated: January 25, 2012
Received: January 30, 2012

Dear Mr. Sampson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K113250

Device Name: Dynatron Tri-wave™ light pad
Dynatron Tri-wave™ light probe

Indications for Use:

Light therapy to provide topical heating for:

Temporary increase in local blood circulation
Temporary relief of minor muscle and joint aches, pains and stiffness
Relaxation of muscles
Muscle spasms
Minor pain and stiffness associated with arthritis

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nick R Ogden for mxn
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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